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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,024	02/23/2004	Veli-Matti Lehtola	13601-016	3763

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,024	LEHTOLA ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 24-30* is/are pending in the application.

4a) Of the above claim(s) *10 and 12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11, and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' RCE, which was filed on 16 June 2008.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 14 May 2008 has been entered.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 11, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Application No. 2005/0215528 ("Furuya").

Furuya discloses a pharmaceutical composition comprising selective estrogen receptor modulator (SERM) drugs (*see* paragraph 0006). The disclosed composition is comprised of:

- the solid drug formulation of instant claim 1 (*see* paragraph 0070);

- the granulates of instant claim 1 (*see* paragraph 0447);
- the compound of formula 1 (*see* paragraph 0125);
- the intra-granular excipients of instant claim 1 (*see* paragraph 0449);
- the disintegrant of instant claim 1 (*see* paragraph 0448);
- the ospemifene of instant claim 2 (*see* paragraph 0125);
- the carboxymethylcellulose of instant claims 3 and 24 (*see* paragraph 0452);
- the diluent (lactose) of instant claims 4 and 25 (*see* paragraph 0070);
- the binder of instant claims 5 and 26 (*see* paragraph 0448);
- the excipient combination of instant claims 6 and 27(*see* paragraph 0448);
- the carboxymethylcellulose of instant claims 7 and 28(*see* paragraph 0452);
- the lactose of instant claims 8 and 29 (*see* paragraph 0070); and
- the dextrin of instant claims 9 and 30 (*see* paragraph 0451).

The wet granulation process disclosed in claim 11 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In any event, Furuya discloses a wet granulation process (*see* paragraph 0494).

Furuya is silent with respect to dissolution profiles. Applicants' composition, as claimed, is the same as the prior art. As, claimed, applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

Furuya explains that the disclosed composition is beneficial as a "…preventative or therapeutic method capable of improving preventative or therapeutic effect of a GnRH agonist on various diseases…" *See* paragraph 0003.

While Furuya does not explicitly teach the ratios of particle sizes and active ingredient concentration range of instant claim 1 or the disintegrant concentration range of instant claims 7 and 28, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine suitable particle size ratios through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Furuya discloses: (a) microcapsule formulations (*see* paragraph 0468) within the size range claimed in instant claim 1, i.e. as small as 2 μm (*see* paragraph 0085); (b) an active ingredient concentration range within the claimed range of instant claim 1 (*see* paragraph 0495); and (c) a disintegrant concentration range within the claimed range of instant claim 7 (*see* paragraph 0512).

Moreover, generally, differences in particle size ratios and concentration will not support the patentability of subject matter encompassed by the prior art unless there is

evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a granulate formulation comprising ospemifiene, as taught by Furuya. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful as a preventative or therapeutic method, as explained by Furuya.

* * * * *

Response to Arguments

Applicants' arguments filed 14 May 2008 have been fully considered but they are not persuasive.

1. Applicants argue, "no *prima facie* case of obviousness has been made since there is no motivation to select the unique combination of ingredients to come up with the claimed formulation for solving the problem at hand" *See* remarks, page 10.

Examiner respectfully submits that the prior art reads on the instant application as claimed. Use of the open-ended transitional term "comprising" leaves the claim susceptible to prior art disclosing elements in addition to those being claimed. See MPEP 2111.03.

Furthermore, Furuya explicitly discloses the same ingredients as are claimed, in concentration ranges that overlap with those claimed, in the same formulation as that claimed (*see* 35 USC 103 rejection, above).

Finally, a difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) ... ."

*

2. Applicants argue, "...the specification establishes clear evidence of unexpected results created by the claimed invention when compared to similar formulations made [sic] direct compression techniques and this evidence has not been rebutted by the Examiner." *See* remarks, page 10.

Examiner respectfully submits that applicants are claiming a formulation, not a method of making a formulation. Evidence of unexpected results using specific techniques is directed to a method of making a formulation.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618